

REMARKS

The Specification has been amended to include the capitalization of GENEWARE. The Applicant has canceled claims 11-14. New claims 19-22 have been added. These changes have been made to place the claims in better form for examination and to further obviate the 35 U.S.C. §102(b), 103(a) and 112 rejections as set forth in the Office Action dated September 9, 2005. It is believed that none of these amendments constitute new matter. It is submitted that these amendments obviate the rejections. Withdrawal of these rejections is respectfully requested.

The Examiner has objected to claims 13 and 14 because of informalities. Applicant has canceled claims 13 and 14 in lieu of new claims 21 and 22. Withdrawal of these objections is respectfully requested.

The Examiner has rejected claims 11-14 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,344,597. It is believed that the Examiner meant to reject claims 11-14 over claims 39-41 and 48 as opposed to claims 1-6 of U.S. Patent No. 6,344,597. Clarification is respectfully requested. Applicant has canceled claims 11-14 in lieu of new claims 19-22. New claim 19 is for the sesquidiploid hybrid species (i.e., diploid for one parental genome and haploid for the other parental genome), hence it is distinct from the interspecific hybrid species of U.S. Patent No. 6,344,597 claim 1 (i.e., diploid for both parental species) and distinct from U.S. Patent No. 6,344,597 claim 39 in which the hybrid species is typically from one parental species with an introgressed trait (i.e., diploid for the recurrent parent and null for the other parent). Therefore, each of the above claims is for a different plant species, and so the methods for generating them are unique and distinct. Applicant has attached a terminal disclaimer form in compliance with 37 CFR 1.321(c). Withdrawal of this rejection is respectfully requested.

The Examiner has rejected claims 11-14 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that the specification lacks a written description of more than *N. excelsior* x *N. benthamiana* to produce *N. excelsiana*. In paragraph [008] of the specification the

Applicant teaches "... conventional approaches to interspecific hybridization ... are (a) diploid x diploid then doubling to produce the allopolyploid and backcrossing to produce the sesquidiploid, ... and (c) autotetraploid x diploid to produce the sesquidiploid directly as described in Technical Bulletin 1586, U.S. Department of Agriculture 1979". In addition to the specific teaching of the *N. excelsiana* example, the Applicant teaches in Table 3 of the specification that the hybrid *N. benthamiana* x *N. tabacum* (BB/TT hybrid) can be backcrossed to the high biomass parent *N. tabacum* to form the sesquidiploid and that the hybrid *N. occidentalis* TW91 x *N. umbratica* TW144 (TW91 x TW144 hybrid or TW144 x TW 91 hybrid) can be backcrossed to the high biomass parent *N. occidentalis* to form the sesquidiploid. Applicant also notes the discussion in paragraph [0041] of the specification of the hybridization of *N. benthamiana* and *N. tabacum*. One of skill in the art given a successful chromosome-doubled interspecific *Nicotiana* hybrid, can choose the greater biomass parent as the recurrent parent and backcross to form the sesquidiploid. Applicant has canceled claims 11-14 in lieu of new claims 19-22. Withdrawal of this rejection is respectfully requested.

The Examiner has rejected claims 11-14 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the specification provides only the *N. excelsiana* example. However, Table 3 of the specification provides for several alternative hybrids including the *N. benthamiana* X *N. tabacum* hybrid, and the *N. occidentalis* X *N. umbratica* hybrids. In addition, Tables 5 and 6 teach the measurement of plant fresh weight ("biomass" as defined in the specification) for exemplary parental species. Such teaching describes how to determine whether the *Nicotiana* plant under evaluation has a biomass greater than the chromosome-doubled interspecific hybrid.

The Examiner states that the "specification fails to teach how many backcross generations are used to produce backcross progeny from interspecific *Nicotiana* hybrids." This rejection is respectfully traversed in that claim 11 (now new claim 19) has exactly one backcross to the chromosome-doubled interspecific hybrid species to generate the sesquidiploid that is the subject of the claim.

The Examiner states that "The specification also teaches colchicine may be needed to restore fertility (see page 2, paragraph [0007] and page 7, paragraph [0041]), thus one of skill in the art would be required to perform undue trial and error experimentation to determine which interspecific *Nicotiana* hybrids produced from the backcross in the claimed method would require an additional step of adding colchicine to induce fertility." This rejection is respectfully traversed in that there is no requirement in claim 11 (now new claim 19) for fertility to be induced. The sesquidiploid can have utility as a host for a viral vector directly, with no additional steps required. Alternatively, if the desired utility envisioned for the sesquidiploid made by the method of claim 11 (now new claim 19) is to use the sesquidiploid as a parent in a further backcrossing scheme (e.g., to introgress a trait into the recurrent parent species), then a skilled artisan would simply use the sesquidiploid as a parent since it is already diploid for the recurrent parent genome (i.e., no colchicine-induced chromosomal doubling would be needed or desired). The desired trait of greater biomass will typically be a complex, multigenic trait, and so neither dominant nor recessive. As the Applicant teaches in the specification, the plants are grown and their biomass (fresh weight) is measured. No undue trial and error experimentation is required. Such plants will either have greater biomass than the parental chromosome-doubled interspecific hybrid (and thus be made by the method of claim 11 (now new claim 19)), and be the subject of claim 13 (now new claim 21) or they will not have greater biomass.

Given the extensive knowledge base in the art from over 50 years of experimentation in making interspecific hybrids of *Nicotiana* species, in addition to the several specific examples taught in the instant specification, and the breadth of the claim covering only those backcrosses that successfully result in sesquidiploid seed to be collected, it is respectfully submitted that it would not require undue trial and error experimentation for one of skill in the art to make and use the invention as broadly claimed. The Applicant has canceled claims 11-14 in lieu of new claims 19-22. Withdrawal of this rejection is respectfully requested.

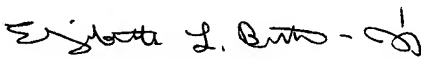
The Examiner has rejected claims 12-13 under 35 U.S.C. 102(b) as being anticipated by McCray (Genetics 17:660-673, 1932). The Examiner argues the claimed invention as reading on any *Nicotiana* seed or parts thereof produced from backcrossing interspecific *Nicotiana* hybrids with a recurrent parent, and that McCray discloses *Nicotiana* seed produced from the backcrossing of interspecific *Nicotiana* hybrids with a recurrent parent. The Applicant has canceled claims 12-13 in lieu of new claims 20-21. The McCray reference does not teach the backcrossing of chromosome-doubled interspecific hybrids with a recurrent parent (e.g., EE/BB x EE = EE/B), but rather teaches the backcross of tri-hybrid species to a diploid parent (e.g., ([*rustica* x *paniculata*] x *langsдорffii*) x *rustica*). The Applicant cites USDA technical Bulletin 1586 as detailing the procedure for generation of a sesquidiploid from a chromosome-doubled interspecific *Nicotiana* hybrid. However, no plants in the cited art references have both a high level biomass and the capacity for high level of systemic expression of heterologous protein from transfection by a viral vector, and no cited art seeds are capable of germinating into such a plant, (i.e., the seed and plant of new claims 20 and 21). Therefore, claims 20 and 21 are novel compared to the McCray reference.

In addition, claims 12 and 13 (now new claims 20 and 21) depend ultimately from claim 11 (now new claim 19) and thus incorporate limitations of claim 11 (now new claim 19). McCray fails to teach all the limitations of claims 12 and 13 (now new claims 20 and 21) (choosing a parent based upon an evaluation of its biomass) and so does not anticipate claims 12 and 13. The cancellation of claims 11-14 in lieu of the new claims 19-22 serve to further distinguish over McCray. Withdrawal of this rejection is respectfully requested.

The Examiner has rejected claim 14 under 35 U.S.C. 103(a) as being patentable over McCray (Genetics 17: 660-673, 1932) in view of Applicant's admission on page 21, paragraph [0071] of the specification. Specifically, the Examiner has rejected claim 14 over McCray in view of the techniques of tissue culture known in the art. McCray does not teach the formation of either chromosome-doubled hybrids or the sesquidiploids resulting from the first backcross. McCray does speculate that, in the formation of his

triple hybrid plants, a (spontaneous) doubling of the gametic chromosome number (from the *rustica* x *paniculata* cross) in the second division of the megaspore mother cell may have occurred with subsequent addition of the haploid number of *langsдорffii* chromosomes, but the resulting tri-hybrid would not constitute a sesquidiploid as defined in the instant application, but rather a triple haploid, perhaps of the form R/P/L. In addition, McCray does not suggest the tissue culturing of sesquidiploids. Applicant has canceled claim 14 in lieu of new claim 22. Withdrawal of this rejection is respectfully requested.

In view of the above amendments and remarks, it is submitted that the claims satisfy the provisions of 35 U.S.C. 102(b), 103(a) and 112. Reconsideration of this application and an early notice of allowance are respectfully requested.

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT REQUIRED					
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